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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/11/1910 07/08/98 BOGGS F-5366

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1M31/0731

RECEIVED  
AUG 06 2001  
FENWAL/PATENT LAW

EXAMINER
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ART UNIT	PAPER NUMBER
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1723  
DATE MAILED: 07/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

CASE.....	F-5366 US
DKT. DATE.....	9-31-01 SEEN BY ATTY.....
FINAL DATE.....	1-31-02 RESP. SENT.....
SUBJECT.....	Office Action / Final

CASE.....	F-5366 US
DKT. DATE.....	10-31-01 SEEN BY ATTY.....
FINAL DATE.....	1-31-02 RESP. SENT.....
SUBJECT.....	Notice of appeal

CASE.....	F-5366 US
DKT. DATE.....	10-31-01 SEEN BY ATTY.....
FINAL DATE.....	1-31-02 RESP. SENT.....
SUBJECT.....	Drawing Correction

# Office Action Summary

Application No.

09/111,915

Applicant(s)

Boggs et al

Examiner

Richard W. Ward

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 7, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 46-66 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☒ Interview Summary (PTO-413) Paper No(s). 22
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 48-50 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the specification as filed for a composite membrane which comprises both a “flat sheet” and a “contoured”, rippled”, or “pleated” sheet. For the purposes of initial examination, it will be assumed that “contoured”, rippled”, and “pleated” sheets fall within the genus of “flat” sheets, and that only one sheet is intended to be present within the membrane (i.e., that antecedent basis errors exist).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 46-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The term "near" in independent claims 46 and 56 is a relative term which renders the claim indefinite. The term "near" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In other words, it is submitted that one having ordinary skill in the art would be unable to determine how close is "near", (e.g., 10 microns? 100 microns?) for the purposes of counting the number of "near" particles and the number of interior particles. As the term "near" is broad, the term can reasonably construed to read on any particulate containing membrane having at least a majority of particulates completely surrounded by a membrane.

Claim 61 recites the limitation "said skin" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 48-50 and 58-60 are vague and confusing, because it is confusing as to how a membrane as described within the instant specification can include both a "flat" sheet and a "contoured", rippled", or "pleated" sheet.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 46-49, 52-55, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al (US 4,728,432). Sugiyama et al [432] discloses a composite membrane comprising particulates contained in a non-fibrous matrix having skin layer (see column 3, lines 29-56; "skin" or surfaces are formed when "prepared by a known method of producing porous membranes...[such as] flowcasting, dipping, coating..."), said non-fibrous matrix being deposited in equal amounts upon a flat sheet support (column 2, lines 49-51), as recited in instant claim 46. Sugiyama et al [432] also discloses: 20 micron particles (column 2, lines 47-48), as recited in instant claim 47; the use of contoured/rippled sheets (column 2, lines 49-56), as recited in instant claims 48-49; polyurethane (column 3, line 47), as recited in instant claim 52; 70 % particulate and 30 % polymer (column 3, line 53), as recited in instant claims 53-54; and polyester mesh supports (column 3, lines 14-28), as recited in instant claim 55. As to claim 66, as there is no statement within the instant specification that the utilized manufacturing process necessarily results in the redistribution of particles, claim 66 is rejected in the same manner as claim 46. As stated within previous office actions, and uncontested to date, the formation of a "skin" layer is deemed to be inherent, as activated carbon (or other "sorbents") would be wetted by polymer solutions, thus surrounding said particles with polymer; at the outer edge of the membrane, the thus wetted sorbents would form an outer "skin" layer of polymer separating the particulates from the outside of the membrane. Also see column 3, line 66 to column 4, line 4 of '432, which indicates that particles are contained firmly within the matrix, unless the matrix is made so thin that it cannot firmly surround the particle. As set forth in MPEP 2112, "Once a reference

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teaching product appearing to be substantially identical is made the basis of a rejection and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to applicant to show an unobvious difference". Also, "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F. 2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

7. Claims 56-59 and 61-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Mahendran et al (US 5,914,039). As to claim 56, '039 discloses a flexible, composite sheet membrane comprising: a polymeric sheet support (column 6, lines 32-43) having a coating of alumina blended with PVDF, and further contains a coating of hydrophilizing polymer (see column 3, lines 54-58). '039 also discloses particle sizes (column 5, lines 45-51), as recited in instant claim 57; supports which are contoured or rippled (column 6, lines 40-43), as recited in instant claim 58-59; distributed particulate (see figures 3-4), as recited in instant claim 61; and PVDF (see above), as recited in instant claim 62.

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*Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 51, 56-59, and 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiyama et al (US 4,728,432) in view of Nakashima et al (US 4,384,954).

As to claim 51, '432 is expanded with respect to depended on claim 46 above. Claim 51 recites the additional limitation of a coating of a hydrophilic agent. '954, which is cited within '432, teaches the optional use of a hydrophilic coating treatment for improving the biocompatibility of an adsorbent material -- see columns 3-4. Maintaining biocompatibility is clearly a concern of '432 -- see column 4, lines 1-4. It would have been obvious to one having ordinary skill in the art at the same time the invention was made to utilize the hydrophilic treatment of '954 in conjunction with the adsorbent system of '432 for the purpose of ensuring product safety by imparting biocompatibility characteristics.

Claims 56 is broader than claim 51 above, and is similarly rendered obvious.

The limitations of claims 57-59 and 61-65 are also disclosed by the '432 reference -- see the 35 USC § 102 rejection above.

10. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiyama et al [432] in view of the conventional state of the art. Sugiyama et al [432] discloses all aspects of

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instant claim 50 except for the use of a pleated sheet. Pleated supports are well-known in the membrane art -- e.g., Markley (US 3,746,175) -- and clearly fit into the genus of supports of Sugiyama et al (column 2, lines 49-54 -- pleated supports have "ruggedness"). In the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the same time the invention was made to utilize such a well known pleated support in place of the generic supports of Sugiyama et al [432] for the purpose of achieving a desired degree of support for a particular separation application.

10. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over '432 in view of '954 as applied to claim 58 above, and further in view of the conventional state of the art.

Claim 60 recites the additional limitation of a pleated support. Pleated supports are well-known in the membrane art -- e.g., Markley (US 3,746,175) -- and clearly fit into the genus of supports of Sugiyama et al (column 2, lines 49-54 -- pleated supports have "ruggedness"). In the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the same time the invention was made to utilize such a well known pleated support in place of the generic supports of '432, as modified by '954, for the purpose of achieving a desired degree of support for a particular separation application.



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*Response to Amendment*

11. The declaration under 37 CFR 1.132 filed 5/7/01 is insufficient to overcome the rejection of claims based upon Sugiyama et al [432] as set forth in the last Office action because:

It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

The examiner is unable to identify any objective evidence within the declaration as filed which indicates that the product as produced by the process of '432 necessarily contains a difference produced by the claimed process. As set forth within the instant specification (see page 16), a redistribution of particles may (but does not necessarily) occur. The declaration does not present experimental data that such redistribution of particles does occur owing to the formation process as opposed to formation mechanisms proposed by the examiner (see prior office actions). To be of probative value, any objective evidence should be supported by actual proof. See MPEP 716.01(c).

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of lack of anticipation and/or obviousness fails to outweigh the evidence of anticipation and/or obviousness.

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*Response to Arguments*

12. Applicant's arguments filed 5/7/01 have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

13. Applicant's arguments regarding Sugiyama et al [432] are not convincing, as applicant has not established that a redistribution of particles occurs within the instant invention owing to the use of a particular production process (nor has applicant clearly claimed such an alleged redistribution of particles). In addition, as stated within previous office actions, and uncontested to date, the formation of a "skin" layer is deemed to be inherent, as activated carbon (or other "sorbents") would be wetted by polymer solutions, thus surrounding said particles with polymer; at the outer edge of the membrane, the thus wetted sorbents would form an outer "skin" layer of polymer separating the particulates from the outside of the membrane. Also see column 3, line 66 to column 4, line 4 of '432, which indicates that particles are contained firmly within the matrix, unless the matrix is made so thin that it cannot firmly surround the particle. As set forth in MPEP 2112, "Once a reference teaching product appearing to be substantially identical is made the basis of a rejection and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to applicant to show an unobvious difference". Also, "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that

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required with respect to product-by-process claims. In re Fitzgerald, 619 F. 2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

### *Conclusion*

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kedem et al (US 5,714,521) demonstrates well-known production processes which involve knife coating (which inherently provides a shearing action) of particulate containing polymer solutions onto a mesh support, and the further treatment of said produced composite membrane to produce a hydrophilic layer. See examples 1 and 2.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard W. Ward whose telephone number is (703)305-0536. The examiner can normally be reached on Monday-Friday from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Walker, can be reached on (703)308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703)305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose phone number is (703)308-0661.

R.W.W.

July 27, 2001



**ANA FORTUNA**  
**PRIMARY EXAMINER**

**Attachment for PTO-948 (Rev. 03/01, or earlier)  
6/18/01**

**The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.**

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities – 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.